

# STATUTES OF THE EORTC BREAST CANCER GROUP

Revised Statutes: December 1995 / February 2001

## 1. Aims of the group

The aims of the Breast Cancer Group are to conduct, develop, coordinate and stimulate research on a clinical basis for the treatment of breast cancer patients. To this end, the Breast Group is fundamentally based on prospective studies.

## 2. Membership

The EORTC Breast Group is a multidisciplinary group and members of the group are **institutions**.

Depending on the number of patients per year entered into the group's trials, institutions can be categorized into

- active members:  $\geq 15$  patients/year
- ordinary members:  $\geq 5$  patients/year and  $< 15$  patients/year

New members receive the status of probationary members for an observational period of two years. During this period, at least 5 patients per year must be entered.

Institutions participating only in specific trials are foreign members.

### Active members:

Active members are expected to contribute at least 15 evaluable patients per year. To become an active member, an institution has to enter at least 15 patients for two consecutive years and to pass the quality control review. When, for two consecutive years, an active member contributes less than 15 evaluable patients per year, it will become an ordinary member.

Active members should attend the twice-yearly meetings of the group regularly. They are represented in the business meeting and have the right to vote for the election of the officers of the group. They participate in the financial and strategic decisions of the group.

### Ordinary members:

Ordinary members have to contribute at least 5 evaluable patients per year. They should attend the twice-yearly group meetings regularly. An ordinary member contributing less than 5 evaluable patients for two consecutive years will be withdrawn from the membership list. An institution whose membership has been withdrawn can re-apply to the group after a waiting period of two years.

### Probationary members:

Any institution active in the fields of clinical and experimental oncology, which agrees to comply with the rules of the group, can apply for probationary membership. Details of how to apply for membership can be found in Appendix I.

A new probationary member is elected by the group for two years. Based on the accrual during these two years, the institution can become an active or an ordinary member.

### Foreign members:

These centers are allowed to participate only in pre-specified trials for which they have received the status of “foreign members”.

This can either relate to:

- Centers belonging to another EORTC group and interested in participating in one particular study of the Breast Group

or

- Centers from other groups (e.g. SAKK, NCIC, ECOG) participating in intergroup studies initiated by the EORTC Breast Group

or

- Centers removed from the probationary members as described in the “Probationary Members” section.

These centers will receive an invitation to the group meetings and a copy of all information relating to the study in which they are participating.

### Observers:

Observers are representatives from centers or from pharmaceutical companies, or anybody who has expressed the wish to remain in contact with the EORTC Breast Group. They will receive an invitation to the open group meetings, which they are welcome to participate in.

NB : Patients recruited in IDBBC studies are taken into account for the membership status of EORTC Breast Group.

## **3. Officers of the group**

Chairman: is elected by the active members of the group for a term of three years . He can be re-elected once for a second three-year term (with the approval of the EORTC Board).

Secretary: is elected by the active members of the group for a term of three years. He can be re-elected once for a second three-year term. The secretary is responsible for the organization of the twice-yearly meetings and the distribution of the minutes to the whole group membership.

The secretary can also hold the function of group treasurer.

The secretary and chairman are responsible for coordination between all members of the group and between the Breast Group and other EORTC groups. They are responsible for providing a yearly report on the activities of the group for submission to the EORTC General Assembly.

Treasurer: is elected by the active members of the group for a term of three years. He can be re-elected once for a second three-year term. A yearly financial report must be submitted to the EORTC treasurer together with a grant application for the following year (if applicable).

Quality Assurance Officer: is elected by the active members of the group for a term of three years. He can be re-elected once for a second term of three years. The quality assurance officer chairs the quality assurance subcommittee of the group.

Study coordinators: are designated by the group and hold office for the duration of a protocol. They should actively take part in the study. They are responsible for the smooth running of the protocol, with the help of the Data Center (DC), and for resolving any difficulties which may arise during the study. They are responsible for the preparation of appropriate publication material, obtaining the agreement of all authors concerned. The role of the study coordinator is fully detailed in Appendix II.

#### **4. Elections**

Active members of the group have the right to vote. Each active institution represents one vote.

The existing officers nominate candidates; all active members can propose other candidates.

The elections will take place during the business meeting or by mail ballots.

#### **5. Group meetings and subcommittees**

The group meetings are organized twice-yearly. A group meeting consists of an open plenary session, a business meeting and several subcommittee meetings.

The open plenary sessions are open to all members and observers.

The business meeting is open to active members only.

During the business meeting, administrative, financial and general problems are discussed.

The subcommittee meetings precede the open plenary sessions:

- The steering committee is in charge of discussing the future strategy of the group. The committee is composed of group officers (the chairman, secretary and treasurer), a representative of the DC and a few representatives of the group. The group representatives are selected from institutions with the highest accrual, taking a diversity of specialties into account.
- The quality assurance subcommittee reviews the performance of the different institutions participating in the group trials.
- Discipline-related subcommittees : pathologists, radiologists.
- The disease stage-related subcommittees discuss new protocols

The subcommittees are nominated by the active members during the business meeting.

## **6. Representation of the group in the General Assembly**

The chairman of the group automatically becomes a full member of the EORTC General Assembly for the duration of his mandate.

## **7. Publications and authorship**

All group publications, oral and written, will have “EORTC” in their title and must be approved by the chairman, the secretary and the study coordinator .

Authorship includes :

- the study coordinator (usually the first author)
- representative(s) of the member institutions which have contributed most of the cases (to be determined per protocol) (co-authors)
- Two EORTC DC representatives are co-authors

Members contributing less than 10% of patients will be included as co-authors by decision of the study coordinator.

Whenever possible, each participating institution will be acknowledged by name and institution.

Manuscripts must be reviewed by all co-authors prior to submission for publication.

All accepted abstracts and publications must be sent to all co-authors, the secretary of the group and the DC.

## **8. Relations with pharmaceutical companies**

Financial support from a pharmaceutical company will be negotiated by the chairman, the medical advisor and the study coordinator. All financial contributions will be put in the group’s fund and allocated after decisions taken by the group during the business meetings.

Any data transfer to the pharmaceutical industry should be approved by the chairman, the medical advisor and the study coordinator.

## **9. The genesis of a new protocol**

New protocols should be presented to and discussed within the disease stage-related subcommittees. Thereafter, proposals are forwarded to the steering committee and to the group by the chairman of the subcommittees.

Upon acceptance by the group, a protocol writing committee will be formed and a study coordinator will be appointed. Further development of the protocol should be done according to the guidelines of the Protocol Review Committee. The guidelines are described in the Investigator’s Handbook and the Breast Cancer Research Manual.

## **10. Participating in an EORTC Breast Group trial**

Any active or probationary member can participate in a group trial after fulfilling the administrative procedure as described in Appendix III. Foreign members can participate only in those trials for which they have received the status of “foreign members”.

## **11. Clinical Trial Data**

Data will not be released from the DC without the permission of the study coordinator, the chairman of the group and the medical advisor/statistician. Data may not be used in oral or written form without the permission of the study coordinator.

## **12. Working Conference (European Breast Cancer Conference – EBCC)**

Every two years, the group organizes, in cooperation with the European Society of Mastology (EUSOMA) and The European Breast Cancer Coalition (Europa Donna), an open working conference on biological and clinical research in breast cancer. The aim is to discuss all new developments in breast cancer research. At this meeting, the results of the ongoing studies of the group are discussed in detail, and aspects which are not covered in ongoing trials are also put on the program. The format is that of a real working conference (review lectures, workshops, report sessions). During this meeting, the statements are developed which set the agenda for the three major organisers of the conference.

## **13. Finances**

The chairman, secretary and treasurer are responsible for the finances of the group. The treasurer is responsible for presenting an overview of the account of the group during the business meeting.

The group's funds are formed by:

1. all financial contributions from pharmaceutical companies for group trials
2. income from the EBCC
3. the EORTC grant (whenever applicable)
4. other sources

Financial support from the group is available for the following circumstances :

- secretarial expenses for the chairman, secretary and treasurer
- the allocation to member institutions (per evaluable patient)
- quality control activities or review of data at participating centers by members of the group
- study coordinators' visits to the DC
- travel expenses of non-members who are invited to group meetings to give presentations
- fellows allocated to specific group projects
- DC statistician and data managers to attend group meetings or protocol specific meetings

Emiel Rutgers  
Secretary

Jacek Jassem  
Chairman

## **APPENDIX I**

### **SUMMARY OF THE PROCEDURE TO BECOME A MEMBER OF THE EORTC BREAST CANCER GROUP**

1. A new center may apply either to the chairman, the secretary or the DC representative. Any application request will be transmitted to the Breast group team at the DC.
2. The DC will send a standard information package to the applying institution which consists of a questionnaire, an overview of the group's ongoing studies and a copy of the statutes. A copy of the letter of application and the reply should be forwarded to the chairman, the secretary and the QA officer.
3. The applicant should return the questionnaire to the DC indicating the studies in which he is interested and the number of patients he expects to enter in these trials. In addition, the applicant must send a copy of his C.V. and the normal laboratory values of his institution.
4. Upon receipt of the questionnaire and the necessary documents, the DC will forward a copy of the questionnaire to the chairman of the quality assurance subcommittee.
5. All applications received at the DC are discussed by the QA subcommittee (by e-mail and if needed during specific QA meetings), who decide whether the application is accepted, with or without site visit or whether is rejected. A written reply is always addressed to the applicant, with copies to the chairman, the secretary and the QA officer.
6. Applicants whose request has been accepted will receive an invitation to the meeting. They may be asked to present their center and activities.
7. On the basis of the information available and the decision of the quality assurance subcommittee, a site visit might be scheduled at the applicant's institution before acceptance of the application. The applicant might be asked to provide financial support for the site visit.

Note: The details related to the membership procedure can be found in the SOP entitled "To become member of the EORTC BCG".

## **APPENDIX II**

### **THE EORTC BREAST GROUP STUDY COORDINATOR (SC)**

The general guidelines have already been described in the two chapters dealing with the responsibilities of EORTC study coordinators in the EORTC Investigator's Handbook and in the EORTC Breast Group manual.

The study coordinator is responsible for the good conduct of the study. In this respect, he will work closely with the Data Manager (DM), the statistician and the medical advisor at the DC for the duration of the study.

Together with the chairman and the medical advisor, the SC will negotiate contracts with the pharmaceutical industry for his trial.

The SC will submit the protocol to the Protocol Review Committee according to their guidelines (see Investigator's Handbook and Breast Cancer Research Manual).

During the conduct of the clinical trial, the SC has the following responsibilities:

1. Trial monitoring

From the start of the study onwards, the SC visits the DC to review the accrual and the data on the patients entered, to evaluate eligibility and to discuss the problems of the study with the DC staff. Finances are provided for two visits a year, including travel (ground transportation or economy class flight ticket) and one night's hotel accommodation, if necessary.

2. Preparation for group meetings

The SC contacts the DM at least one month before the meeting to discuss the tables to be included in the report for the group meeting. The DM will send the prepared tables to the SC one week before the meeting. The SC will check the tables and request additional information if necessary. If the SC does not contact the DM, minimum information for the trial will be prepared.

3. Group meetings

The SC will present the data of his study at meetings and discuss the status and the results with the group.

4. Distribution of information, study forms and protocols

Study forms and protocols, at the start of each new study, are sent from the administrative secretariat to the centers listed in the protocol, together with a letter from the study coordinator. During the trial, protocol and forms can either be sent from the secretariat or the SC. Subsequent amendments to protocols and/or study forms should follow the same route as for the activation of the protocol.

## **APPENDIX III**

### **PARTICIPATING IN AN EORTC BREAST GROUP TRIAL**

The investigator must contact the EORTC Data Manager of the trial:

Data Manager of trial "*trial-No*"  
EORTC Data Center  
Ave. E. Mounier 83 /11  
1200 Brussels  
Tel: +32 2 774 16 04  
Fax: +32 2 772 35 45

The data manager will reply by a letter, requesting the following information:

- Curriculum vitae (if not yet available)
- Normal laboratory values (if not yet available)
- Ethics Committee approval for this specific protocol
- Commitment Statement (which includes disclosure of potential conflict of interest)

The data manager will put an institution on the list of authorized participants only upon receipt of the required information. This will enable the institution to enter patients into the trial. The procedure on how to enter patients into a trial is described in each trial protocol.